

REMARKS

For convenience, Pages 2 and following of the official action are presented below with

105 corresponding responses interspersed between paragraphs:

Restriction to one or the following inventions is required under 35 U.S.C. 121:

110 *I. Claims 1-9 drawn to a composition comprising a first compound including metal atoms/ions and a second compound containing a non-shielded purine or pyrimidine bound to a portion of the metal atoms/ions, and an apparatus comprising said compounds, classified in class 435, subclass 283.1.*

115 *II. Claims 10-17, drawn to a method for separating compounds using an IMAC composition, classified in class 435, subclass 288.6.*

III. Claims 18-20, drawn to an assay for measuring fluorescence using an IMAC composition, classified in class 435, subclass 288.7

120 *The inventions are distinct, each from the other because of the following reasons:*

Inventions Group I and Groups III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product of Group I can be used in any of the materially distinct processes set forth in Groups II-III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, the nonpatent literature required for each of these inventions are not co-extensive; hence said [Page 3] searches would be burdensome. Therefore

125 *restriction for examination purposes as indicated is proper.*

130

Applicant has provisionally elected a Group as required. However, this requirement of election is respectfully traversed. Group I relates to Groups I-III are all related to the separation of biotech moieties and are closely related.

135 *Inventions Group II and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and are not disclosed as capable of being used together. Specifically, the method of Group II does not require a step wherein the differential fluorescence of a nucleic acid is measured; and the assay of Group III does not require a step wherein a particular compound is separated from another. As such, the inventions have different method steps resulting in different modes of operation. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, the non-patent literature*

140 *searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.*

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The statutory basis of restriction practice under Section 121, provides that if two or more independent and distinct inventions are claimed in one patent application, the Examiner may require the application be restricted to one invention. This authority is discretionary, not mandatory. Accordingly, Applicant respectfully requests that such discretionary authority not be invoked and the restriction requirement be withdrawn.

Please refer to the MPEP 802.01 Meaning of "Independent" and "Distinct":

35 U.S.C. 121 quoted in the preceding section states that the Commissioner may require restriction if two or more "independent and distinct" inventions are claimed in one application. In 37 CFR 1.141, the statement is made that two or more "independent and distinct inventions" may not be claimed in one application.

This raises the question of the subjects as between which the Commissioner may require restriction. This, in turn, depends on the construction of the expression "independent and distinct" inventions.

"Independent", of course, means not dependent. If "distinct" means the same thing, then its use in the statute and in the rule is redundant. If "distinct" means something different, then the question arises as to what the difference in meaning between these two words may be. The hearings before the committees of Congress considering the codification of the patent laws indicate that 35 U.S.C. 121: "enacts as law existing practice with respect to division, at the same time introducing a number of changes."

The report on the hearings does not mention as a change that is introduced, the subjects between which the Commissioner may properly require division.

The term "independent" as already pointed out, means not dependent. A large number of subjects between which, prior to the 1952 Act, division had been proper, are dependent subjects, such, for example, as combination and a subcombination thereof; as process and apparatus used in the practice of the process; as composition and the process in which the composition is used; as process and the product made by such process, etc. If section 121 of the 1952 Act were intended to direct the Commissioner never to approve division between dependent inventions, the word

185 "independent" would clearly have been used alone. If the Commissioner
has authority or discretion to restrict independent inventions only, then
restriction would be improper as between dependent inventions; e.g., such
as the ones used for purpose of illustration above. Such was clearly,
however, not the intent of Congress. Nothing in the language of the statute
190 and nothing in the hearings of the committees indicate any intent to change
the substantive law on this subject. On the contrary, joinder of the term
"distinct" with the term "independent", indicates lack of such intent. The
law has long been established that dependent inventions (frequently
termed related inventions) such as used for illustration above may be
195 properly divided if they are, in fact, "distinct" inventions, even though
dependent.

INDEPENDENT

200 The term "independent" (i.e., not dependent) means that there is no
disclosed relationship between the two or more subjects disclosed, that is,
they are unconnected in design, operation, or effect, for example: (1)
species under a genus which species are not usable together as disclosed
or (2) process and apparatus incapable of being used in practicing the
process.

205 DISTINCT

The term "distinct" means that two or more subjects as disclosed are
related, for example, as combination and part (subcombination) thereof,
process and apparatus for its practice, process and product made, etc., but
210 are capable of separate manufacture, use, or sale as claimed, AND ARE
PATENTABLE (novel and unobvious) OVER EACH OTHER (though
they may each be unpatentable because of the prior art). It will be noted
that in this definition the term related is used as an alternative for
dependent in referring to subjects other than independent subjects.
215 Note that the Claims in the Groups (Composition, Method and Assay)
must be patentable over each other for restriction to be properly required.
Here the composition and the method and the assay stem from the same
novel point and one can only speculate on whether they would be
patentable over each other. A single Example encompasses all three
220 Groups and Applicant respectfully urges that the restriction requirement
be withdrawn.

Clearly, there is a very close relationship between the Groups I, II and III inventions. As stated above, 35 U.S.C. Section 121 requires the Examiner to find that the inventions be
225 independent and distinct. Also see, Torok v. Watson, Com'r Pats., 122 F. Supp. 788, 103 U.S.P.Q. 78 (DC 1954). The Examiner has not supported his finding. To support a conclusion to require restriction, an Examiner must provide supporting reasons and/or examples. M.P.E.P. §803.

230 Applicant respectfully disagrees with the Examiner's above quoted rationale. Group I Claims are drawn to a composition, Group II Claims are drawn to a method of using, and Group III Claims are drawn to a method of assay. All claims are related in that they all relate to utilizing IMAC as an element. The Examiner's requirement to restrict should, therefore, be withdrawn.

235 *The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all of the limitations of the allowable product*
240 *claims will be rejoined in accordance with provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection, or allowance, whichever is earlier. [Page 4], amendments submitted after Final Rejection are governed by 37 CFR 1.116, amendments submitted after Allowance are governed by 37 CFR 1.312.*

245 *In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product*
250 *claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product-claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C 103," 1184. OG 86: (Murch 26, 1996).Zig. [996]. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claim should be amended during prosecution either to*
255 *maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder in accordance with the above policy. Further, note that the prohibition against double patenting rejections of 35 U.S.C 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP§804.01.*

260 *Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).*

Applicant has noted the rejoinder matters, helpfully set forth above by the Examiner, and has provisionally elected a Group as required. However, this requirement of election is respectfully traversed. Groups I-III are all related to the separation of biotech moieties and are closely related.

[Page 5]

Applicant is reminded that-upon the cancellation of claims to a nonelected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants' Attorney has reviewed the elected Claims and finds no change in inventorship is required by the election.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272 0771. The examiner can normally be reached on 6:30am-to 4pm, Mon.-Fri., first Friday off

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D., can be reached on (571) 272 0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from the Patent application Retrieval (PAIR) system. Status information for unpublished applications is available through Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866 217 9197 (toll-free).
David A. Lambertson, Ph.D.

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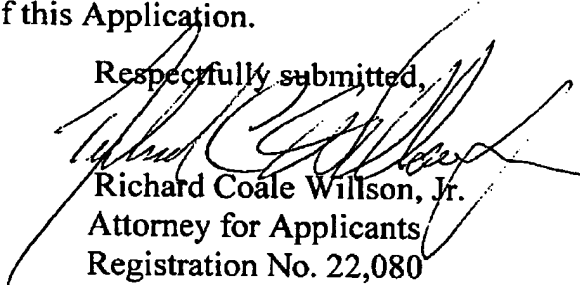
JAMES KETTER
PRIMARY EXAMINER

The claims have been provisionally elected and clarified merely by addition of wording from the original specification "Modifications" section. No new matter has been added and no estoppel is involved. The changes were not required by prior art. No references were cited.

300 Any necessary (small entity) charges can be charged to USPTO Deposit Account 20-336
of Technology Licensing Co. LLC. Correspondence may be addressed to Customer No.
26830.

305 The Examiner is especially invited to telephone Applicants' Attorney if that would
expedite prosecution and disposal of this Application.

Respectfully submitted,



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